Inte lal Application No PCT/IB2004/003043

A. CLASSIFICATION OF SUBJECT MATTER IPC 7 A61K31/015 A61K31/136 IPC 7 A61P23/00 A61P29/00 According to International Patent Classification (IPC) or to both national classification and IPC B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) IPC 7 A61K Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practical, search terms used) EPO-Internal, WPI Data, PAJ, BIOSIS, EMBASE C. DOCUMENTS CONSIDERED TO BE RELEVANT Category ° Citation of document, with indication, where appropriate, of the relevant passages Relevant to claim No. WO 03/040084 A (MERZ PHARMA GMBH & CO. X 1,6-10, KGAA; PARSONS, CHRISTOPHER, GRAHAM, 13,14 RAPHAEL; HE) 15 May 2003 (2003-05-15) claims 6,9 WO 99/01416 A (MERZ + CO. GMBH & CO) X 1,6-10,14 January 1999 (1999-01-14) 13,14 claims 1,12 page 46, line 26 page 46, line 29 WO 01/98253 A (MERZ + CO. GMBH & CO) X 1,6-10, 27 December 2001 (2001-12-27) 13,14 claims 1,8,9 Further documents are listed in the continuation of box C. Patent family members are listed in annex. Special categories of cited documents: "T" tater document published after the International filing date or priority date and not in conflict with the application but "A" document defining the general state of the art which is not cited to understand the principle or theory underlying the considered to be of particular relevance invention "E" earlier document but published on or after the international "X" document of particular relevance; the claimed invention filing date cannot be considered novel or cannot be considered to "L" document which may throw doubts on priority claim(s) or involve an inventive step when the document is taken alone which is cited to establish the publication date of another "Y" document of particular relevance; the claimed invention citation or other special reason (as specified) cannot be considered to involve an inventive step when the document is combined with one or more other such docu-O document referring to an oral disclosure, use, exhibition or ments, such combination being obvious to a person skilled other means in the art. *P* document published prior to the International filing date but later than the priority date claimed '&' document member of the same patent family Date of the actual completion of the international search Date of mailing of the international search report 08/03/2005 1 March 2005 Name and mailing address of the ISA **Authorized officer** European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Beranová, P Fax: (+31-70) 340-3016

PCT/IB2004/003043

C.(Continu	ation) DOCUMENTS CONSIDERED TO BE RELEVANT	PC1/1B200	7 000043
Category °	Citation of document, with indication, where appropriate, of the relevant passages		Relevant to claim No.
X	PARSONS C G ET AL: "Memantine and the amino-alkyl-cyclohexane MRZ 2/579 are moderate affinity uncompetitive NMDA receptor antagonists: In vitro characterisation" AMINO ACIDS, SPRINGER VERLAG, AU, vol. 19, no. 1, 2000, pages 157-166, XP002292645 ISSN: 0939-4451 page 163, last paragraph		1,6-10, 13,14
A	DANYSZ W ET AL: "AMINO-ALKYL-CYCLOHEXANS AS A NOVEL CLASS OF UNCOMPETITIVE NMDA RECEPTOR ANTAGONISTS" CURRENT PHARMACEUTICAL DESIGN, BENTHAM SCIENCE PUBLISHERS, SCHIPHOL, NL, vol. 10, no. 10, 2002, pages 835-843, XP008030349 ISSN: 1381-6128 page 842, paragraph 5		

International application No. PCT/IB2004/003043

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)
This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:
1. X Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:
Although claims $1-24$ are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).
Box III Observations where unity of Invention is lacking (Continuation of Item 3 of first sheet)
This International Searching Authority found multiple inventions in this international application, as follows:
1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
Remark on Protest The additional search fees were accompanied by the applicant's protest.
No protest accompanied the payment of additional search fees.
restricted to the invention first mentioned in the claims; It is covered by claims Nos.: Remark on Protest The additional search fees were accompanied by the applicant's protest.

information on patent family members

Intel Inal Application No
PCT/IB2004/003043

Patent document cited in search report		Publication date		Patent family member(s)	Publication date
WO 03040084	A	15-05-2003	CA	2465738 A1	15-05-2003
			EP	1442008 A1	04-08-2004
			WO	03040084 A1	15-05-2003
			HU	0402028 A2	28-01-2005
			US	2003166634 A1	04-09-2003
WO 9901416		14-01-1999	AT	240936 T	15-06-2003
			AU	724974 B2	05-10-2000
			AU	8804298 A	25-01-1999
			CA	2292558 A1	14-01-1999
			CZ	9904571 A3	14-06-2000
			DE	69814878 D1	26-06-2003
			DE	69814878 T2	19-05-2004
			DK	1009732 T3	22-09-2003
			EA	2254 B1	28-02-2002
			WO	9901416 A2	14-01-1999
			EP	1009732 A2	21-06-2000
			ES	2200358 T3	01-03-2004
			FI	992801 A	29-12-1999
			HK	1029574 A1	12-11-2004
			HU	0100266 A2	29-05-2002
			IL	133235 A	19-02-2004
			JP	2002511873 T	16-04-2002
			NO	996548 A	28-02-2000
			PL	337809 A1	11-09-2000
			PT	1009732 T	31-10-2003
			TW	593225 B	21-06-2004
			US	6071966 A	06-06-2000
			US	6034134 A	07-03-2000
			ZA	9805678 A	10-01-2000
WO 0198253	Α	27-12-2001	AU	8186101 A	02-01-2002
			CA	2410852 A1	27-12-2001
			CZ	20030497 A3	18-08-2004
			WO	0198253 A2	27-12-2001
			EP	1303477 A2	23-04-2003
			HU	0301551 A2	28-11-2003
			JP	2004501130 T	15-01-2004
			NO	20026103 A	19-02-2003
			PL	359583 A1	23-08-2004
			TW	593223 B	21-06-2004
			ZA	200104187 A	22-11-2002

PATENT COOPERATION TREATY

PCT

REC'D 2 9 AUG 2005

WIPO

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

pplicant's or agent's file referen	FOR FURTHER ACTIO	
08.86811 International application No.	International filing date (day)	Priority date (day/month/year) 28.07.2003
CT/IB2004/003043	on (IPC) or national classification and IPC	
applicant MERZ PHARMA GmbH This report is the interport of the interport o	& Co. KGaA ernational preliminary examination reported as and transmitted to the applicant at sts of a total of 6 sheets, including this	: Cover siteer.
This report is also ac	companied by ANNEXES, comprising	u) a total of sheets, as follows:
☐ sheets of and/or sheets of and/or sheets	rative Instructions).	ed by this Authority (see Rule 70.16 and Section 607 of the
beyond to the income to the in	nental Box. International Bureau only) a total of (inc	ich this Authority considers contain an amendment that goes cation as filed, as indicated in item 4 of Box No. I and the dicate type and number of electronic carrier(s)), containing a computer readable form only, as indicated in the Supplemental 2 of the Administrative Instructions).
Box Relating	to Sequence Listing (see Section 80)	2 of the Administrative Instructions).
Box Relating	g to Sequence Listing (see Section 802	
Box Relating 4. This report contain	g to Sequence Listing (occording)	
4. This report contain	s indications relating to the following its	ems:
Box Relating 4. This report contain Box No. I Box No. II Box No. III	s indications relating to the following its Basis of the opinion Priority Non-establishment of opinion with rega	
Box Relating 4. This report contain Box No. I Box No. II Box No. III	s indications relating to the following its Basis of the opinion Priority Non-establishment of opinion with regar	ems: ard to novelty, inventive step and industrial applicability
Box Relating 4. This report contain Box No. I Box No. II Box No. III Box No. IV Box No. V	s indications relating to the following its Basis of the opinion Priority Non-establishment of opinion with regal Lack of unity of invention Reasoned statement under Article 35(applicability; citations and explanations	ems: ard to novelty, inventive step and industrial applicability 2) with regard to novelty, inventive step or industrial
Box Relating 4. This report contain Box No. I Box No. II Box No. III Box No. IV Box No. V Box No. V	s indications relating to the following its Basis of the opinion Priority Non-establishment of opinion with regal Lack of unity of invention Reasoned statement under Article 35(applicability; citations and explanations Certain documents cited	ems: ard to novelty, inventive step and industrial applicability 2) with regard to novelty, inventive step or industrial such statement
Box Relating 4. This report contain Box No. I Box No. II Box No. III Box No. IV Box No. V Box No. V Box No. VI	s indications relating to the following its Basis of the opinion Priority Non-establishment of opinion with regal Lack of unity of invention Reasoned statement under Article 35(applicability; citations and explanations Certain documents cited Certain defects in the international app	ems: ard to novelty, inventive step and industrial applicability 2) with regard to novelty, inventive step or industrial supporting such statement
Box Relating 4. This report contain Box No. I Box No. II Box No. III Box No. IV Box No. V Box No. V Box No. VI	s indications relating to the following its Basis of the opinion Priority Non-establishment of opinion with regal Lack of unity of invention Reasoned statement under Article 35(applicability; citations and explanations Certain documents cited	ems: ard to novelty, inventive step and industrial applicability 2) with regard to novelty, inventive step or industrial supporting such statement
Box Relating 4. This report contain Box No. I Box No. II Box No. III Box No. IV Box No. V Box No. V Box No. VI Box No. VIII Box No. VIII	s indications relating to the following its Basis of the opinion Priority Non-establishment of opinion with regardack of unity of invention Reasoned statement under Article 35(applicability; citations and explanations) Certain documents cited Certain defects in the international application observations on the internation	ems: ard to novelty, inventive step and industrial applicability 2) with regard to novelty, inventive step or industrial supporting such statement
Box Relating 4. This report contain Box No. I Box No. II Box No. III Box No. IV Box No. V Box No. V Box No. VI	s indications relating to the following its Basis of the opinion Priority Non-establishment of opinion with regardack of unity of invention Reasoned statement under Article 35(applicability; citations and explanations) Certain documents cited Certain defects in the international application observations on the internation	ems: ard to novelty, inventive step and industrial applicability 2) with regard to novelty, inventive step or industrial supporting such statement plication nal application
Box Relating 4. This report contain Box No. I Box No. II Box No. III Box No. IV Box No. V Box No. VI Box No. VI Box No. VIII Box No. VIII	s indications relating to the following its Basis of the opinion Priority Non-establishment of opinion with regardack of unity of invention Reasoned statement under Article 35(applicability; citations and explanations) Certain documents cited Certain defects in the international application observations on the internation	ems: ard to novelty, inventive step and industrial applicability 2) with regard to novelty, inventive step or industrial supporting such statement plication nal application
Box Relating 4. This report contain Box No. I Box No. II Box No. III Box No. IV Box No. V Box No. V Box No. VI Box No. VIII Date of submission of the 28.02.2005	s indications relating to the following its Basis of the opinion Priority Non-establishment of opinion with regal Lack of unity of invention Reasoned statement under Article 35(applicability; citations and explanations Certain documents cited Certain defects in the international application observations on the internation demand ss of the International otherity:	ems: ard to novelty, inventive step and industrial applicability 2) with regard to novelty, inventive step or industrial supporting such statement plication nal application Date of completion of this report
Box Relating 4. This report contain Box No. I Box No. II Box No. III Box No. IV Box No. V Box No. V Box No. VI Box No. VIII Date of submission of the 28.02.2005	s indications relating to the following its Basis of the opinion Priority Non-establishment of opinion with regal Lack of unity of invention Reasoned statement under Article 35(applicability; citations and explanations Certain documents cited Certain defects in the international application observations on the internation demand ss of the international opinions. Patent Office - Gitschiner Str. 103	ems: ard to novelty, inventive step and industrial applicability 2) with regard to novelty, inventive step or industrial supporting such statement plication nal application Date of completion of this report 26.08.2005

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No. PCT/IB2004/003043

	Вох	No. I Basis of the report
1.	With filed	regard to the language, this report is based on the international application in the language in which it was, unless otherwise indicated under this item.
		This report is based on translations from the original language into the following language, which is the language of a translation furnished for the purposes of: ☐ international search (under Rules 12.3 and 23.1(b)) ☐ publication of the international application (under Rule 12.4) ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2:	hav	n regard to the elements* of the international application, this report is based on <i>(replacement sheets which</i> e been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this ort as "originally filed" and are not annexed to this report):
	Des	cription, Pages
	1-24	as originally filed
	Cla	ms, Numbers
	1-2	as originally filed
		a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3.		The amendments have resulted in the cancellation of: ☐ the description, pages ☐ the claims, Nos. ☐ the drawings, sheets/figs ☐ the sequence listing (specify): ☐ any table(s) related to sequence listing (specify):
4	. □ ha Su	This report has been established as if (some of) the amendments annexed to this report and listed below do not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the pplemental Box (Rule 70.2(c)). The description, pages the claims, Nos. the drawings, sheets/figs the sequence listing (specify): any table(s) related to sequence listing (specify):
	*	If item 4 applies, some or all of these sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No. PCT/IB2004/003043

		No. III Non-establishment o	f opi	nion with regard to novelty, inventive step and industrial	
1.	The obv	questions whether the claimed ious), or to be industrially applica	inven able ł	tion appears to be novel, to involve an inventive step (to be non- nave not been examined in respect of:	
		the entire international applicati	on,		
	\boxtimes	claims Nos. 1 - 24			
		because:			
		the said international application, or the said claims Nos. 1 - 24 (with respect to industrial applicability) relate to the following subject matter which does not require an international preliminary examination (specify):			
		see separate sheet			
		the description, claims or drawings (indicate particular elements below) or said claims Nos. are so unclear that no meaningful opinion could be formed (specify):			
		the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.			
		no international search report h	nas b	een established for the said claims Nos.	
		the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:			
		the written form		has not been furnished	
				does not comply with the standard	
		the computer readable form		has not been furnished	
				does not comply with the standard	
		the tables related to the nucleon not comply with the technical r	otide a equir	and/or amino acid sequence listing, if in computer readable form only, do ements provided for in Annex C-bis of the Administrative Instructions.	
		See separate sheet for further	deta	ls	

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY Internation PCT/IB26

International application No. PCT/IB2004/003043

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Yes: Claims

2 - 5, 11, 12, 15 - 24

No: Claims

1, 6 - 10, 13, 14

Inventive step (IS)

Yes: Claims

No:

Claims

1 - 24

Industrial applicability (IA)

- Yes: Claims

No: Claims

2. Citations and explanations (Rule 70.7):

see separate sheet

PCT/IB2004/003043

Re Item III.

3.1 Claims 1 - 24 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

Re Item V.

- 5.1 The following documents are referred to in this communication:
 - D1: WO 03/040084 A (MERZ PHARMA GMBH &; CO. KGAA; PARSONS, CHRISTOPHER, GRAHAM, RAPHAEL; HE) 15 May 2003 (2003-05-15)
 - D2: WO 99/01416 A (MERZ + CO. GMBH &; CO) 14 January 1999 (1999-01-14)
 - D3: WO 01/98253 A (MERZ + CO. GMBH &; CO) 27 December 2001 (2001-12-27)
 - D4: PARSONS C G ET AL: "Memantine and the amino-alkyl-cyclohexane MRZ 2/579 are moderate affinity uncompetitive NMDA receptor antagonists: In vitro characterisation" AMINO ACIDS, SPRINGER VERLAG, AU, vol. 19, no. 1, 2000, pages 157-166, XP002292645 ISSN: 0939-4451
 - D5: DANYSZ W ET AL: "AMINO-ALKYL-CYCLOHEXANS AS A NOVEL CLASS OF UNCOMPETITIVE NMDA RECEPTOR ANTAGONISTS" CURRENT PHARMACEUTICAL DESIGN, BENTHAM SCIENCE PUBLISHERS, SCHIPHOL, NL, vol. 10, no. 10, 2002, pages 835-843, XP008030349 ISSN: 1381-6128
- 5.2 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1, 6 10, 13 and 14 is not new in the sense of Article 33(2) PCT.

Document **D1** discloses the same compounds as claimed by the present application and their use for the treatment of chronic and acute pain and migraine (claims 6 and 9).

D2 shows the same compounds as NMDA receptor antagonists and their use for the treatment of chronic and acute pain (claims 1 and 12; page 46, lines 26 and 29).

D3 teaches about the same compounds and their use for the treatment of pain (claims 1, 8 and 9).

D4 reports that a strong evidence exists that MRZ 2/579 (= neramexane) could be useful for the treatment of chronic pain (page 163, last paragraph).

PCT/IB2004/003043

The above documents are therefore considered to be relevant for novelty and inventive step of the subject-matter of claims 1, 6 - 10, 13 and 14.

5.3 Concerning inventive step, the following is pointed out:

The present application differs from the above cited prior art in the condition treated (chronic and acute pain and migraine in D1 - D4 and hyperalgesia, allodynia and neuropathic pain in the present application).

The problem to be solved by the present application may be regarded as providing for compounds useful for the treatment of the above listed conditions.

First, it is considered that the difference between chronic and acute pain and hypersensitivity to pain is very minor. Furthermore, D5 reports that a first lb phase clinical trial to evaluate the effect of neramexane on hyperalgesia and allodynia has been set up recently (page 842, 5th paragraph). The skilled person would therefore regard the use of 1-amino-alkylcyclohexane derivatives such as neramexane for the treatment of hyperalgesia and allodynia as an obvious option in order to solve the problem posed.

In view of the cited documents, the subject-matter of claims 1 - 24 lacks inventive step (Article 33(3) PCT).

5.4 For the assessment of the present claims 1 - 24 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL APPLICATION STATUS FORM (IASF)

Date of issue of this IASF:

(the information contained in this IASF reflects the status of the international application as of this date)
09 February 2006 (09.02.2006)

From the	INTERNATIONAL	BUREAU
----------	---------------	--------

I	•	Į	C

UNITED STATES PATENT AND TRADEMARK OFFICE Commissioner for Patents, P.O.Box 1450 Alexandria VA 22313 -1450 ETATS-UNIS D'AMERIQUE

-1	International application number:	PCT/IB2004/003043
-2		
	International filing date:	28 July 2004 (28.07.2004)
I-3	Earliest priority date:	28 July 2003 (28.07.2003)
I-4 	Title of the invention:	THE USE OF 1-AMINO- ALKYLCYCLOHEXANE COMPOUNDS IN THE TREATMENT OF PAIN HYPERSENSITIVITY
I-5	International Patent Classification:	⁷ A61K 31/015, 31/136, A61P 23/00, 29/00
I-6	Language of filing:	English
I-7	The State for which the Office acts as a designated Office has been designated in the international application:	Yes
I-7-1	Indication of the State(s) designated in the international application in respect of which the Office acts as a designated Office (only where the designated Office is a regional Office):	Not applicable
I-7-2	The international application has been considered withdrawn in a declaration made by the receiving Office on (date):	Not applicable
I-7-3	The international application or the designation of the State for which the Office acts as a designated Office has been withdrawn by the applicant (date on which withdrawal became effective):	Not applicable
1-7-4	Kind of protection or treatment:	Patent
I-7-4-1	Identification of parent application or parent grant:	Not applicable
I-8	Date of receipt of record copy by the International Bureau:	20 September 2004 (20.09.2004)
I- 9	Applicant(s) and/or inventor(s) for the State(s) for which th	e Office acts as a designated Office
I-9-1	Applicant and/or inventor	
I-9-1-1	Data currently on record	
I-9-1-1-1	Applicant's and/or inventor's name:	MAGERL, Walter
I-9-1-1-2	Address:	Kästrich 12d 55116 Mainz Germany
1-9-1-1-3	State of nationality:	DE
I-9-1-1-4	State of residence:	DE

I-9-1-1-5	This person is:	Applicant and inventor
l-9-1-2	Data previously on record (in case of a change recorded by the International Bureau under Rule 92bis):	No data previously on record available for inclusion in this IASF; any such data is available from the IB.
I-9-1-3	Indication of the State(s) designated in the international application for the purposes of which the person is an applicant and/or inventor (only where the designated Office is a regional Office):	Not applicable
1-9-2	Applicant and/or inventor	
1-9-2-1	Data currently on record	
I-9-2-1-1	Applicant's and/or inventor's name:	KLEIN, Thomas
I-9-2-1-2	Address:	Freiherr vom Stein Str. 17 55257 Budenheim Germany
I-9-2-1-3	State of nationality:	DE
I-9-2-1-4	State of residence:	DE
I-9-2-1-5	This person is:	Applicant and inventor
I-9-2-2	Data previously on record (in case of a change recorded by the International Bureau under Rule 92bis):	No data previously on record available for inclusion in this IASF; any such data is available from the IB.
I-9-2-3	Indication of the State(s) designated in the international application for the purposes of which the person is an applicant and/or inventor (only where the designated Office is a regional Office):	Not applicable
I-9-3	Applicant and/or inventor	
1-9-3-1	Data currently on record	
I-9-3-1-1	Applicant's and/or inventor's name:	TREEDE, Rolf-Detlef
I-9-3-1-2	Address:	Theodor-Storm-Weg 11 55127 Mainz Germany
I-9-3-1-3	State of nationality:	DE
I-9-3-1 - 4	State of residence:	DE
I-9-3-1-5	This person is:	Applicant and inventor
I-9-3-2	Data previously on record (in case of a change recorded by the International Bureau under Rule 92bis):	No data previously on record available for inclusion in this IASF; any such data is available from the IB.
I-9-3-3	Indication of the State(s) designated in the international application for the purposes of which the person is an applicant and/or inventor (only where the designated Office is a regional Office):	Not applicable
I-10	The international application contains sequence listings and/or tables filed under Section 801(a) of the Administrative Instructions:	No
I-11	The following declaration(s) referred to in Rule 4.17 made Office acts as a designated Office was (were) contained in by the International Bureau before the expiration of the time	the international application as filed or received
I-11-1	Declaration(s) as to the identity of the inventor (Rules 4.17 (i) and 51bis.1(a)(i)):	Not applicable
I-11-2	Declaration(s) as to the applicant's entitlement, as at the international filing date, to apply for and be granted a patent (Rules 4.17(ii) and 51bis.1(a)(ii)):	Not applicable
I-11-3	Combined declaration(s) as to the identity of the inventor (Rules 4.17(i) and 51bis.1(a)(i)) and the applicant's entitlement, as at the international filing date, to apply for and be granted a patent (Rules 4.17(ii) and 51bis.1(a)(ii)):	Not applicable

I-11-4	Declaration(s) as to the applicant's entitlement, as at the international filing date, to claim the priority of the earlier application (Rules 4.17(iii) and 51bis.1(a)(iii)):	Not applicable
I-11-5	Declaration(s) of inventorship (only for the purposes of the designation of the United States of America) (Rules 4.17 (iv) and 51bis.1(a)(iv)):	Not applicable
I-11-6	Declaration(s) as to non-prejudicial disclosures or exceptions to lack of novelty (Rules 4.17(v) and 51bis.1(a) (v)):	Not applicable
II - PRIO	RITY CLAIM(S)	
II-1	Number of earlier application:	60/490,865
II-1-1	Filing date of earlier application:	28 July 2003 (28.07.2003)
II-1-2	Country in which, or regional Office or receiving Office with which earlier application was filed (where the earlier application is an ARIPO application, indication of the country party to the Paris Convention or Member of the World Trade Organization for which that earlier application was filed):	
II-1-3	Priority document received at the International Bureau on:	08 November 2004 (08.11.2004)
II-1-4	Priority document submitted or transmitted in compliance with Rule 17.1(a) or (b) (only where priority document was received at the International Bureau):	Yes
II-1-5	Applicant has requested the receiving Office to prepare and transmit the priority document in compliance with Rule 17.1(b) (only where no priority document was received at the International Bureau):	Not applicable
II-1-6	Priority claim withdrawn by a notice from the applicant (date on which withdrawal became effective; if the notice of withdrawal was received by the International Bureau after completion of technical preparations for international publication, such withdrawal will not have been reflected in the pamphlet) (Rule 90bis.3):	
II-1-7	Declaration by the receiving Office or the International Bureau that priority claim is considered, for the purposes of the procedure under the Treaty, not to have been made (date of declaration) (Rule 26bis.2(b)):	Not applicable
II-2	Number of earlier application:	60/526,825
II-2-1	Filing date of earlier application:	02 December 2003 (02.12.2003)
11-2-2	Country in which, or regional Office or receiving Office with which earlier application was filed (where the earlier application is an ARIPO application, indication of the country party to the Paris Convention or Member of the World Trade Organization for which that earlier application was filed):	
II-2-3	Priority document received at the International Bureau on:	08 November 2004 (08.11.2004)
II-2-4	Priority document submitted or transmitted in compliance with Rule 17.1(a) or (b) (only where priority document was received at the International Bureau):	Yes
II-2-5	Applicant has requested the receiving Office to prepare and transmit the priority document in compliance with Rule 17.1(b) (only where no priority document was received at the International Bureau):	Not applicable
II-2 - 6	Priority claim withdrawn by a notice from the applicant (date on which withdrawal became effective; if the notice of withdrawal was received by the International Bureau after completion of technical preparations for international publication, such withdrawal will not have been reflected in the pamphlet) (Rule 90bis.3):	

11-2-7	Declaration by the receiving Office or the International Bureau that priority claim is considered, for the purposes o the procedure under the Treaty, not to have been made (date of declaration) (Rule 26bis.2(b)):	Not applicable
II-3	Number of earlier application:	60/537,215
II-3-1	Filing date of earlier application:	16 January 2004 (16.01.2004)
11-3-2	Country in which, or regional Office or receiving Office with which earlier application was filed (where the earlier application is an ARIPO application, indication of the country party to the Paris Convention or Member of the World Trade Organization for which that earlier application was filed):	
11-3-3	Priority document received at the International Bureau on:	08 November 2004 (08.11.2004)
II-3-4	Priority document submitted or transmitted in compliance with Rule 17.1(a) or (b) (only where priority document was received at the International Bureau):	Yes
11-3-5	Applicant has requested the receiving Office to prepare and transmit the priority document in compliance with Rule 17.1(b) (only where no priority document was received at the International Bureau):	Not applicable
11-3-6	Priority claim withdrawn by a notice from the applicant (date on which withdrawal became effective; if the notice of withdrawal was received by the International Bureau after completion of technical preparations for international publication, such withdrawal will not have been reflected in the pamphlet) (Rule 90bis.3):	
II-3-7	Declaration by the receiving Office or the International Bureau that priority claim is considered, for the purposes of the procedure under the Treaty, not to have been made (date of declaration) (Rule 26bis.2(b)):	Not applicable
III - INTE	RNATIONAL SEARCH REPORT	
III-1	International Searching Authority carrying out the international search:	ISA/EP
III-2	International search report or declaration under Article 17 (2)(a) received by the International Bureau:	Yes
III-3	Corrected version(s) of the international search report (if any) received by the International Bureau:	Not applicable
IV - REF	ERENCE TO DEPOSITED BIOLOGICAL MATERIAL	Not applicable
V - INTE	RNATIONAL PUBLICATION	
V-1	International publication number:	WO 2005/009421 (A3)
V-2	International publication date:	03 February 2005 (03.02.2005)
V-3	Language of publication:	English
V-4	Number of figure of drawing published together with the abstract:	Not applicable
V-5	Republication(s) (republication date(s) and reason(s)):	10 March 2005 (10.03.2005) (A2) Correction of entry in Section I of the PCT Gazette 21 April 2005 (21.04.2005) (A3) Later publication of international search report
VI - INTI	ERNATIONAL PRELIMINARY REPORT ON PATENTABILITY	(CHAPTER I)
VI-1	International preliminary report on patentability (Chapter I) issued by the International Bureau on:	
VI-2	Corrected version(s) of the international preliminary report on patentabilty (Chapter I) (if any) issued by the	Information not available for inclusion in this IASF

	International Bureau on:		
VII - INTERNATIONAL PRELIMINARY EXAMINATION			
VII-1	A demand electing the State(s) for which the Office acts as an elected Office has been received by the International Preliminary Examining Authority (where the elected Office is a regional Office, indication of the State(s) elected in respect of which the Office acts as an elected Office):	Yes 28 February 2005 (28.02.2005)	
VII-2	The election was made before/after the expiration of 19 months from the priority date:	Before	
VII-3	The election or the demand containing the election of the State(s) for which the Office acts as an elected Office has been considered not to have been made or submitted in a declaration made by (the International Bureau/the competent International Preliminary Examining Authority) on (date):	Not applicable	
VII-4	The election or the demand containing the election of the State(s) for which the Office acts as an elected Office has been withdrawn by the applicant (date on which withdrawal became effective being the date of receipt of the notice of withdrawal by the International Bureau) (Rule 90is.4):	Not applicable	
VII-5	International Preliminary Examining Authority carrying out international preliminary examination:	IPEA/EP	
VII-6	International preliminary examination report received by the International Bureau:	No	
VII-7	Corrected version(s) of the international preliminary examination report (if any) received by the International Bureau:	Information not available for inclusion in this IASF	

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Idhir Britel
Facsimile No. +41 22 740 14 35	e-mail pct.cor@wipo.int Telephone No. +41 22 338 83 38